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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
KHARE, DEVESH

ART UNIT	PAPER NUMBER
1623	11

DATE MAILED: 12/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Status of the Restriction

The response to restriction requirement received on 10/22/02 has been entered. Applicants' election of Group I (claims 1-16) with traverse in Paper No. 10 is acknowledged. In view of the similarity between the circulatory related conditions to be treated in the instant claims, the election of species between hypertension, vasodilation, and ischemia is withdrawn. Applicant's arguments are convincing.

Claims 17-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-20 are currently pending in this application. An action on the merits of claims 1-16 is contained herein below.

Objections to the Specification

The abstract of the disclosure is objected to because its content fails to enable the reader thereof, regardless of his or her degree of familiarity with patent documents, to ascertain quickly the character of the subject matter covered by the technical disclosure and also fails to include that which is new in the art to which the instant invention pertains. Correction is required. See MPEP § 608.01(b).

Objections to the Claims

Claim 10 is objected to for failing to end in a period. Correction is required.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

1. Claims 1-9 and 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: R_1, R_2, R_3, R_4, R_5 and R_6 in claim 1. Claim 1 is unclear with regard to the phrase "R_1, R_2, R_3, R_4, R_5 and R_6 are each chemical residues" because chemical residues are not defined.

2. Claims 2-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Substituted "alkyl groups" do not appear to be supported. There appears to be insufficient antecedent basis for "substituted" alkyl groups, in view of the fact that the Markush group in claim 3 does not provide support for substituted alkyl moieties as part of the compound claimed.

3. Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of alternative uses for the composition of claim 1 in claims 11-15 fails to further limit the pharmaceutical composition since intended use as a treatment modality fails to result in a structural difference in the composition of matter claimed and is afforded no patentable weight. Only one pharmaceutical composition claim dependent from claim 1 is necessary. The additional claims are substantial duplicates and should be cancelled.

Additionally, claims 11-15 are confusing. Each composition claim, which recites the phrase "to the mammal in need thereof", is awkward and confusing. In all occurrences

in the composition claims wherein this recitation is set forth, the claims are indefinite, and the phrase should be deleted.

4. Claim 13 is rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 fails to further limit the composition claim from which it depends since the recitation of the intended use as a treatment modality fails to result in a structural difference in the composition of matter claimed and is afforded no patentable weight.

5. Claim 15 is rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the phrase "a sympathetic blocking agent" is intended to include the compound of claim 1 where chemical residues are not defined.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 8 and 11-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Myers et al. (U.S. Patent 6,376,472, filed Oct. 16,1998).

The compound of claim 1 represent an adenosine 2',3'-O-isopropylidene analogue, wherein R_1, R_2, R_3, R_4, R_5 and R_6 could have the meaning of a hydrogen or any chemical residue in the absence of a defined chemical residue.

Myers et al. disclose a compound of the formula where the ribose ring of the adenosine is 2',3'-O-isopropylidene derivative (see claim 1). In columns 7 and 8, the depiction of formula I and the disclosure of the following variables anticipates the compound of claim 1 as instantly claimed. See specifically column 7, lines 52-63, wherein formula I shows an adenosine nucleoside compound. The prior art compound anticipates applicant's instant invention when variables A and B are OR' and OR" and together these variables represent the structure in column 8, lines 41-44 and the R' and R" variables may be hydrogen or alkyl, column 8, lines 46-50; wherein the variable T is the alkyl alcohol group $R_3O\text{-}CH_2$ set forth in column 8, line 25; wherein R_6 is hydrogen and X-Y of the prior art is seen to be a chemical residue. Pharmaceutical compositions of the invention as claimed are anticipated by the disclosure in column 45, lines 26-42; wherein adenosine analogues as disclosed may be formulated into pharmaceutical compositions.

4. Claim 10 is free of the prior art. Claim 10 contains a compound where the 2',3'-O-isopropylidene is substituted by "$-CH_2-CH_2-CH_2-CH_2-N-(CH_3)_3$" group, which is not taught or fairly suggested by the prior art of the record.

State of the Art References

The following references further reflect the current state of the art:

Box et al. (U.S. Patent 6,407,076)- discloses adenosine analogues as agonists of the adenosine A1 receptor.

Olsson et al. (U.S. RE37,045)- discloses N-6 substituted-5'-(N-substituted carboxamide) adenosines as cardiac vasodilator and antihypertensive agents.

Zablocki et al. (U.S. Patent 6,294,522)- discloses N^6 heterocyclic 8-modified adenosine derivatives.

Ellis et al. (U.S. Patent 5,998,388)- discloses adenosine derivatives.

Stein et al. (U.S. Patent 4,167,565)- discloses adenosine 5'-carboxamides and method of use.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is (703)605-1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 703-308-4624. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD(3Y).
Art Unit 1623
December 3,2002

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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